

### **Remarks/Arguments**

Applicants have received and carefully reviewed the Office Action of the Examiner mailed March 4, 2009. Currently, claims 1-4, 16-29, and 31-41 remain pending of which claims 11, 12, and 14 were previously withdrawn. Claims 1-10, 13, 16-29, and 31-41 have been rejected. Claims 1, 26, and 33 have been amended to emphasize that the device is delivered in a non-collapsed position and assumes a collapsed position when deployed. Claims 2 and 3 have been amended to correct an informality. Favorable consideration of the following remarks is respectfully requested.

### **Claim Rejections – 35 USC § 103**

Claims 1-10, 13, 16-29, and 31-41 were rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. (U.S. Patent No. 6,312,446), hereinafter Huebsch, in view of Redmond et al. (U.S. Patent No. 6,334,865), hereinafter Redmond and Lafontaine et al. (U.S. Patent No. 5,964,782), hereinafter Lafontaine. After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). Nowhere does Huebsch appear to disclose “a closure component including a collapsible backing movable between a non-collapsed delivery position, in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing”. Furthermore, nowhere does Huebsch appear to disclose, “collapsed deployed position, in which the backing center portion is collapsed proximally toward the backing periphery to have a generally disc shape” or “a plurality of fibrous tissue engaging members disposed on the backing and oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction, the fibrous tissue engaging members entangling the backing when the backing is in the collapsed position”. Additionally, the Examiner acknowledges that Huebsch does not disclose “the collapse actuator assuming a deformed profile solely in response to a sufficiently proximal force

applied to the collapse actuator in order to permit the detachable end to pass proximally through the distal aperture”; “the collapsible backing made of pile or fabric, wherein the pile engaging hooks engage portions of the pile backing to retain the pile backing in the collapsed position”; “bioabsorbable materials”; or “[t]he collapse actuator having a frangible connection to the distal end of the closure component”.

Instead, Huebsch appears to disclose “a device comprising a cylindrical shaft of metal or polymeric material with concentric parallel cuts through the wall of the device which create flattened parallel support struts. The center of the support struts move radially away from the axis in a hinge like fashion in response to movement of the device’s proximal and distal ends toward the center of the device”. (Abstract, emphasis added) Although the Examiner has characterized the entire device (200) of Huebsch as “a collapsible backing or support”, presumably intending to specify elements (22) and (222), the disclosure of Huebsch refers to elements (22) and (222) consistently as struts which fold at hinge points (24,255). The struts (22,222) of device (200) do not appear to assume “a non-collapsed delivery position, in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing”, but instead assume a generally cylindrical form as shown in Figs. 2, 5A, 5B, 6, 9, 14, and 18-20. It appears that the Examiner may have inadvertently reversed the delivery and deployed positions of the device (200) of Huebsch in this portion of the discussion; however the delivery position of the device of Huebsch approximates a cylinder rather than a distally tapering cone and the deployed position resembles a bipyramid (Fig. 4, 5A, 5B, 24, and 25) rather than a disk. The collapsed position of the device of Huebsch appears to be properly identified in the discussion of actuation.

The Examiner turns to Lafontaine in an effort to supply the bioabsorbable backing with tissue or adventitia engaging hooks that entangle in the backing located proximal of the hooks as the backing moves from the non-collapsed position to the collapsed position to retain the backing in a collapsed configuration, citing Figs. 34A-34C. Even were the struts of Huebsch to be covered with the bioabsorbable backing of Lafontaine, the hooks would not appear to be capable of engaging with the backing. Hooks disposed along the distal portions of the distal struts and along the proximal portions of the proximal struts do not appear to be positioned to come in contact with backing located on other parts of

the device as they would face away from the intervening tissue wall and not toward another strut with or without attached backing. Hooks disposed along the proximal portions of the distal struts and along the distal portions of the proximal struts would appear to be prevented from contacting the pile of the opposing strut for the reason that they are separated by the intervening tissue and spaced apart by the central portion (18,218) of the device. Further, the device of Huebsch is retained in its deployed position not by hooks engaging pile, but rather by the engagement of one or more internal locks. Further still, the cylindrical ring of Figs. 34A-34B does not appear to provide a generally conical shape in a non-collapsed delivery position which element appears to be missing from Huebsch. Huebsch in view of Lafontaine appears to be incapable of combination to achieve the necessary configuration of hooks which may engage pile to overcome the deficiencies of Huebsch. In addition, the proposed combination would also appear to impermissibly alter the principle of operation of both Huebsch and Lafontaine. (MPEP 2143.01, VI)

Further, the elements (270) of Huebsch have been identified by the Examiner as “proximally facing tissue engaging hooks”; however the plurality of fibrous tissue engaging members of claim 1 are “disposed on the backing”, “engage the backing when the backing is in the collapsed position” and “are oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction”. Hooks (70,270) of Huebsch appear to be disposed on the struts (22,222) rather than on a backing; appear to be incapable of contacting an opposing strut in the collapsed deployment position across the intervening gap; and appear to be oriented to engage tissue when traveling in a distal direction as they protrude from the struts on both sides of the central portion (18,218), particularly in the deployment configuration in which they would pass through the tissue aperture. Lafontaine appears to be silent with respect to the orientation of hooks associated with a backing other than to note that they are capable of engaging tissue as the device is withdrawn and that interior hooks may engage interior pile of the backing. As illustrated, at least some of the hooks associated with a backing appear to be randomly oriented or transversely oriented such that they would present an engaging orientation when moved either distally or proximally.

Redmond, said to teach a flexible collapse actuator wire, does not appear to overcome the noted deficiencies of Huebsch in view of Lafontaine as applied to independent claims 1, 26, and 33. Therefore, Huebsch in view of Lafontaine and Redmond does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness and Applicants respectfully request that the rejections be withdrawn.

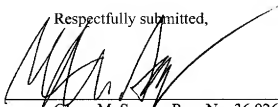
If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

For at least this reason, it is believed that claims 2-10, 13, 16-25, 27-29, 31, 32, and 34-41, which depend from non-obvious claims 1, 26, and 33 respectively, are also nonobvious and Applicants respectfully request that the rejections be withdrawn.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

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Respectfully submitted,



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